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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,192	06/23/2006	Takayuki Oniki	0171-1287PUS1	3847

2292 7590 09/15/2010
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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
09/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,192	ONIKI ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,26,27,30-32,34,35,38,39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,26,27,30-32,34,35,38,39,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/21/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/17/2010 has been entered. New claim 42 has been added.

Applicant's arguments filed 08/17/2010 and 09/01/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 23-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oniki et al. (WO 03/030851) in view of Takeda et al. (US 2001/0007652); and the rejection is applicable to new claim 42.

Applicant argues that the Takeda dentifrice composition contains significant amounts of water as an essential component. All the working examples of Takeda are

more water based. Therefore, should one of skill in the art actually combine the disclosure of Takeda and Oniki, this would lead to a composition containing water, and thus not the instantly claimed nonaqueous gel. The Takeda and Oniki compositions/methods involve large amounts of water. As a result, the shellac of Takeda is not properly dissolved, and thus cannot penetrate into the enamel of teeth. Takeda merely coats the teeth to give a whitening effect which does not last for a long time. Applicant cites paragraph [0018] of Takeda as evidence that shellac dissolves in substances commonly used in the conventional dentifrice compositions such as propylene glycol. Since a considerable amount of water is present in the dentifrice composition of Takeda, shellac is not dissolved, but is present as an undissolved solid or paste in the resulting dentifrice composition; and the compound which is able to dissolve shellac such as propylene glycol is only present in an insufficiently small amount.

The Examiner disagrees.

Since the rejection is a 103 obviousness rejection, neither Takeda nor Oniki is required to teach each and every limitation of the instant claims. Further, the working examples are not representative of the entire scope of the specification. Oniki et al. is the primary reference in the rejection and Takeda et al. is only cited to disclose the use of shellac as a component that can change the optical properties of teeth. As cited in the Non-final office action dated 08/19/2009, Oniki clearly discloses that the whitening component is one or more selected from lower alcohols having four or less carbon atoms, such as ethanol, isopropyl alcohol, n-propanol and n-butanol; glycols having ten

or less carbon atoms such as propylene glycol, diethylene glycol, ethylene glycol, dipropylene glycol and 1,3-butylene glycol; polyethylene glycols, such as those having a molecular weight of 200-800; glycerin and diglycerin. **The whitening component can be used in conjunction with water in a ratio as high as 100/0, i.e. no water**. The amount of whitening component should preferably be 20% to 100% of the entire composition, see pages 4 and 5. Accordingly, Oniki et al. discloses nonaqueous compositions comprised of propylene glycol in amounts preferably form 20% to 100%. The paragraph cited by Applicant only provides motivation for using nonaqueous compositions comprised of propylene glycol, i.e. proplyene glycol/water ratio of 100/0, when incorporating the shellac of Takeda et al. with the composition of Oniki et al. As cited in the Non-final office action, Takeda et al. disclose that gels, pastes and liquids are possible forms of the dentifrice, see page 5. Takeda et al. also disclose that the composition is mixed into a uniform viscous liquid and into a uniform toothpaste, see Takeda [0022]. It would reasonably be assumed that the gels and liquids would also be uniform dentifrices without undissolved shellac present.

Applicant argues that the shellac of Takeda et al. does not infiltrate the enamel of teeth. It may cover the surface of teeth in a pasty state, which also prevents infiltration of polyols. The precipitated shellac or wax on the surface of teeth is brittle and easily removed form the surface of teeth. Thus, the whitening effect does not endure for a long time.

The Examiner disagrees.

As cited *supra*, Oniki et al. discloses nonaqueous compositions comprised of from 20% to 100% propylene glycol. Takeda et al. discloses that the numerous flaws on teeth cause their brightness to be lessened; and that the shellac covers the surface of teeth, thereby smoothing them, see Takeda et al. [0039]. One of ordinary skill would reasonably expect that the shellac of Takeda et al. fills in the flaws on enamel of teeth to provide a smooth covering, when applied as a gel. Further, as cited in the Non-final office action dated 08/19/2009, the disclosure that shellac changes the optical properties on teeth provides adequate motivation for incorporating it in the composition of Oniki et al. since they both are used for the same purpose, see page 6. When incorporating of the shellac of Takeda et al. is into compositions of Oniki et al. one of ordinary skill would reasonably take the disclosure of paragraph [0018] of Takeda et al. cited by Applicant into consideration and prepare compositions comprised of propylene glycol in order to dissolve the shellac. Since the shellac would be dissolved in the propylene glycol, both propylene glycol and shellac would reasonably be expected to infiltrate the flaws of the enamel, especially with the disclosure of Oniki that the whitening components of the composition infiltrate the tooth enamel, see page 4. Accordingly, the compositions/methods suggested by combining Oniki et al. and Takeda et al. read on the claimed invention; and would reasonably be expected to reversibly make teeth look white. There is no limitation in the instant claims as to the length of time of the whitening effect.

Applicant argues that Takeda fails to disclose or teach the application of the nonaqueous gel composition by using the special tool of the inventive set and method and feature thereof as instantly claimed.

The Examiner disagrees.

As cited *supra*, Oniki et al. is the primary reference and Takeda et al. is only cited to disclose the use of shellac as a component that can change the optical properties of teeth. As cited in the Non-final office action dated 08/19/2009, Oniki et al. disclose that the whitening composition should preferably be applied to teeth in concert with a special tool which retains and keeps it in position in contact with teeth, prevents the composition from dissolving and dilution by saliva and eliminates unpleasant feeling. It may be formed from a water-insoluble material in the form of a tape, sheet or film. The tools should be formed from materials such as polyethylene, foamed polyethylene, polypropylene, polyester, rayon, pulp, cotton, silk and paper. The duration of application is 1 to 120 minutes per dosage, see page 5. Accordingly, once motivation is provided for incorporation of the shellac of Takeda et al. into the compositions of Oniki et al. it would have been obvious to use the methods of Oniki et al. to apply the modified compositions.

Applicant argues since the cited references use aqueous compositions, that there is improper rationale for combining the references since the shellac would not properly dissolve.

The Examiner disagrees.

The Examiner's response to Applicant's arguments concerning aqueous compositions is provided *supra*.

Applicant argues that Oniki is improperly combined with Takeda since it fails to disclose the use of the ingredient B. However Takeda fails to disclose the acrylic acid copolymers of the ingredient B, therefore the use of the acrylic copolymers as the ingredient of B are not expected from Takeda. The amount of polyols in Takeda et al. is fewer than the amount of the inventive tooth whitening set/method.

The Examiner disagrees.

As cited *supra* and in the Non-final office action, adequate motivation has been provided for incorporating the shellac of Takeda et al. into the compositions of Oniki et al., which are comprised of from 20%-100% of polyol, see page 6. Further, as cited in the Non-final office action, shellac is comprised of hydroxypalmitic acid, i.e. a C_{16} fatty acid, see page 6. The claims are drawn to "at least one C_{14-22} higher fatty acid and/or acrylic acid copolymer". Accordingly, the shellac of Takeda et al. read on the limitations of the claim.

Applicants allege that the present invention has achieved unexpected and superior results in terms of the whitening effect and duration thereof. Applicant cites the Declarations filed 08/17/2010 as evidence of said allegation. Applicant argues that whiteness is achieved in differently than in the cited art and provides a depiction illustrating the mechanism of action of the instant invention.

The Examiner disagrees.

As cited in the Non-final office action dated 08/19/2009, Oniki et al. clearly disclose that the whitening component of the compositions infiltrate the tooth enamel; and discloses propylene glycol as a whitening component in amounts from 20% to 100%, see page 4. Accordingly, if the shellac of Takeda et al. is incorporated into the composition of Oniki et al. it would reasonably be expected to be dissolved in the propylene glycol and infiltrate the tooth enamel also.

Applicant allege that the instant compositions provide superior results over working examples of Takeda and Oniki and directs the Examiner to Table 1 for evidence of said allegation.

Table 1 is not persuasive. The composition of Takeda et al., i.e. Comparison 1, is comprised of only 8% propylene glycol and 3% glycerin, i.e. 11% polyol. Since Oniki et al. disclose that propylene glycol and glycerin are both whitening components that change the optical properties of teeth in amounts of 20% to 100%, it would be reasonably expected that a composition comprised of only 11% polyols would not possess the whitening effect of one comprised of 98%, i.e. invention 1, and 89%, i.e. invention 2, of the whitening component and the whitening effect would reasonably be expected to last longer. Similarly, the composition of Oniki, i.e. Comparison 2, is not comprised of shellac. Since, Takeda et al. discloses that shellac changes the optical properties of teeth, it is not unexpected that a composition comprising of 98%, i.e. invention 1, and 89%, i.e. invention 2 of the whitening component along with shellac would provide enhance whitening effect over a composition comprised of 10%

isopropanol and 30% propylene glycol, i.e. 40% whitening components, and that the whitening effect would last longer.

After analyzing, even assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate in scope with those findings. In Table 1, Applicant has only used 93% propylene glycol, Invention 1, and 89% propylene glycol, i.e. Invention 2, not any tooth whitening ingredient selected from isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-360, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol, and glycerin, not polyethylene glycol with an average molecular weight of 190-360, butylene glycol, and glycerin, not any ingredient having a relative permittivity of 17.0 to 43.0 (at 25°) and a vapor pressure of 0 to 7000 kPa, and not in any amount form 50% to 99.5%; has only used 1% Eudragit L100 and 5% shellac respectively, not any substance selected from myristic acid, 7-hydroxymyristic acid, jalaric acid, 9,10,16-trihydroxypalmitic acid, palmitoleic acid, 12-hydroxystearic acid, isostearic acid, oleic acid, linoleic acid, linolenic acid, erucic acid, shellac, t-Bu acrylate/ethyl acrylate/methacyrlate acid copolymer, methyl acrylate/methacrylic acid copolymer, methyl methacrylate/methacrylic acid copolymer, acrylic acid/acrylamide/ethyl acrylate copolymer, octylacrylamide/acrylate ester copolymer, and methyl methacylate/ethyl acrylate/methacrylic acid triethyammonium ethyl chloride copolymer, not any one selected from isostearic acid , shellac, t-Bu acrylate/ethyl acrylate/methacyrlate acid copolymer, acrylic acid/acrylamide/ethyl acrylate copolymer, octylacrylamide/acrylate ester copolymer, and methyl methacylate/ethyl acrylate/methacrylic acid triethyammonium ethyl chloride

copolymer, not at least one selected from and C_{14-C22} higher fatty acids and/or acrylic acid copolymers, and not in any amount from 0.1 to 10%; and has only used 6% hydroxypropyl cellulose in both Invention 1 and Invention 2, not any gelling agent, not any gelling agent selected from polyacrylic acid, carboxyvinyl polymer, hydroxypropyl cellulose, carboxymethylcellulose and salts thereof, and not in any amount from 0.1 to 15%; has only used a polyurethane film, not any material selected from polyethylene, foamed polyethylene, polypropylene, foamed polypropylene, polyester, rayon, polyurethane, pulp, cotton, silk, paper, metal foil, silicone rubber, natural rubber, vinyl acetate resin, acrylic resin, and ethylene-vinyl acetate resin; and has only applied the composition to teeth for 3 minutes, not any time between 1 and 120 minutes. Accordingly, the scope of the claims is much broader.

The remainder of Applicant's arguments from the Declaration have been address *supra*.

No claims are allowed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612